AMENDMENTS TO THE CLAIMS

Claim 1 (Currently Amended): A pharmaceutical gel preparation comprising a mixture of:

(a) at least one pharmaceutically active ionic peptide compound having a length of from 8 to 12 amino acids in lyophilized form at a concentration of from 5 to 50 ~~mixed in a predetermined amount of the value $X_{optimum}$ in~~ mg of peptide per ml of the preparation, and

(b) ~~with~~ an aqueous solution of an inorganic or acetic acid salt ~~in a predetermined~~ at a concentration of from 0.01% to about 0.9% (weight/volume), ~~the value $Y_{optimum}$ in % weight/volume,~~ and wherein the preparation is suitable for administration either immediately after the mixing of (a) and (b) ~~the administration can take place immediately,~~ or after a standing time of up to about 120 minutes subsequent to the mixing of (a) and (b), ~~preferably between about 10 to about 120 minutes, particularly preferably between about 15 to 60 minutes is observed, and it being possible for the value $X_{optimum}$ to be selected by a test method A including the stages of administration of various amounts where X_n is the number of different amounts n, where $n \geq 1$ in mg of the peptide as a mixture with an isotonic aqueous solution of mannitol onto or to a test system and selection of the amount $X_{optimum}$ in mg of peptide per ml of mixture which provided in the experiment the most favorable blood plasma levels of the peptide in the test system in relation to C_{max} the maximum blood plasma concentration and t_{max} the time until C_{max} is reached, and the concentration $Y_{optimum}$ being selected by a test method B including the stages of administration of the amount $X_{optimum}$ in mg of peptide per ml of mixture of the peptide as a mixture with aqueous solutions which differ in the concentration where Y_n is the number of different concentrations n, where $n \geq 1$ in % weight/volume onto or to a test system and selection of the concentration $Y_{optimum}$ in % weight/volume was fixed as the concentration which in the experiment resulted in the highest~~

~~value for the plasma concentration C_{active}, where $C_{min} < C_{active} > C_{max}$ where C_{min} = lowest plasma concentration of the peptide at which the peptide still has an adequate pharmaceutical effect in the experiment while at the same time, it has an influence on the time t_{active} until the highest concentration in the plasma is reached, where $t_{active} > t_{max}$.~~

Claim 2 (Previously Presented): The pharmaceutical preparation as claimed in claim 1, wherein the pharmaceutically active ionic peptide compound is cationic.

Claim 3 (Withdrawn): The pharmaceutical preparation as claimed in claim 1, wherein the pharmaceutically active ionic peptide compound is anionic.

Claim 4 (Previously Presented): The pharmaceutical preparation as claimed in claim 1, wherein the pharmaceutically active ionic peptide compound is a mono-, di- or multi-valent cationic or anionic peptide.

Claim 5 (Withdrawn): The pharmaceutical preparation as claimed in claim 1, wherein the pharmaceutically active ionic peptide compound is a mono-, di- or multi-valent ampholytic peptide.

Claims 6 – 7 (Canceled):

Claim 8 (Previously Presented): The pharmaceutical preparation as claimed in claim 1 wherein the pharmaceutically active ionic peptide compound is a GnRH analog.

Claim 9 (Previously Presented): The pharmaceutical preparation as claimed in claim 1 wherein the pharmaceutically active ionic peptide compound is a GnRH antagonist.

Claim 10 (Previously Presented): The pharmaceutical preparation as claimed in claim 1 wherein the pharmaceutically active ionic peptide compound is selected from the group consisting of cetrorelix, teverelix, abarelix, ganirelix, azaline B, antide, detirelix, ramorelix, degarelix, D-63153 or their pharmaceutically active salt and mixtures thereof.

Claim 11 (Previously Presented): The pharmaceutical preparation as claimed in claim 1 wherein the pharmaceutically active ionic peptide compound is the GnRH antagonist D-63153.

Claim 12 (Previously Presented): The pharmaceutical preparation as claimed in claim 1 wherein the inorganic salt or the acetic acid salt is a physiologically tolerated salt.

Claim 13 (Previously Presented): The pharmaceutical preparation as claimed in claim 1 wherein the aqueous inorganic salt or acetic acid salt is selected from the group consisting of sodium chloride, calcium chloride, magnesium chloride, sodium acetate, calcium acetate, magnesium acetate and mixtures thereof.

Claim 14 (Previously Presented): The pharmaceutical preparation as claimed in claim 1 wherein the mixture of the pharmaceutically active ionic peptide compound and of the aqueous solution of the inorganic salt or of the acetic acid salt is a liquid suspension or a semisolid dispersion.

Claim 15 (Canceled):

Claim 16 (Currently Amended): The pharmaceutical preparation as claimed in claim 1 wherein the ~~amount X~~ concentration of the pharmaceutically active ionic peptide compound is in the range from about 10 to about 50 mg per ml of the total amount of the pharmaceutical preparation.

Claim 17 (Currently Amended): The pharmaceutical preparation as claimed in claim 1 wherein the ~~amount X~~ concentration of the pharmaceutically active ionic peptide compound is in the range from about 20 to about 30 mg per ml of the total amount of the pharmaceutical preparation.

Claim 18 (Currently Amended): The pharmaceutical preparation as claimed in claim 1 wherein the ~~amount X~~ concentration of the pharmaceutically active ionic peptide compound is in the region of about 25 mg per ml of the total amount of the pharmaceutical preparation.

Claim 19 (Canceled):

Claim 20 (Currently Amended): The pharmaceutical preparation as claimed in claim 19 wherein D-63153 is the pharmaceutically active ionic peptide compound, and the ~~amount X~~ concentration is in the range from about 10 to about 50 mg per ml of the total amount of the pharmaceutical preparation.

Claim 21 (Currently Amended): The pharmaceutical preparation as claimed in claim 19 wherein D-63153 is the pharmaceutically active ionic peptide compound, and the ~~amount X~~ concentration is in the range from about 20 to about 30 mg per ml of the total amount of the pharmaceutical preparation.

Claim 22 (Currently Amended): The pharmaceutical preparation as claimed in claim 19 wherein D-63153 is the pharmaceutically active ionic peptide compound, and the ~~amount X~~ concentration is in the region of about 25 mg per ml of the total amount of the pharmaceutical preparation.

Claims 23 – 24 (Canceled):

Claim 25 (Currently Amended): The pharmaceutical preparation as claimed in claim 1 wherein the ~~concentration Y~~ concentration of the aqueous inorganic or acetic acid salt solution is in the range from about 0.05% to about 0.5% (weight/volume).

Claim 26 (Currently Amended): The pharmaceutical preparation as claimed in claim 1 wherein the ~~concentration Y~~ concentration of the aqueous inorganic or acetic acid salt solution is about 0.1% (weight/volume).

Claim 27 (Currently Amended): The pharmaceutical preparation as claimed in claim 1 wherein the inorganic salt is sodium chloride~~, and in that the concentration Y concentration is equal to or less than about 0.9% (weight/volume)~~.

Claim 28 (Canceled):

Claim 29 (Currently Amended): The pharmaceutical preparation as claimed in claim 1 wherein the inorganic salt is sodium chloride, and in that the ~~concentration Y~~ concentration is in the range from 0.05% to about 0.5% (weight/volume).

Claim 30 (Currently Amended): The pharmaceutical preparation as claimed in claim 1 wherein the inorganic salt is sodium chloride, and in that the ~~concentration Y~~ concentration is about 0.1% (weight/volume).

Claim 31 (Previously Presented): The pharmaceutical preparation as claimed in claim 1 wherein at least one of the pharmaceutically active ionic peptide compound is D-63153, and the inorganic salt is sodium chloride.

Claim 32 (Currently Amended): The pharmaceutical preparation as claimed in claim 1 wherein at least one of the pharmaceutically active ionic peptide compound is D-63153, and the ~~amount X~~ concentration thereof is about 25 ~~ml per~~ mg per ml of the preparation, and in that the inorganic salt is sodium chloride, and the ~~concentration Y~~ concentration thereof is about 0.1% (weight/volume).

Claim 33 (Currently Amended): A method for producing a pharmaceutical preparation comprising the steps A) bringing together ~~an amount $X_{optimum}$ in mg per ml of the finished preparation of~~ said at least one pharmaceutically active peptide compound in

lyophilized form and an aqueous solution of an inorganic or acetic acid salt ~~in a concentration with the value $Y_{optimum}$ (% weight/volume)~~ and B) mixing the components.

Claim 34 (Previously Presented): The method for producing a pharmaceutical preparation as claimed in claim 33, wherein the pharmaceutically active ionic peptide compound is D-63153, and the inorganic salt is sodium chloride.

Claim 35 (Currently Amended): The method for producing a pharmaceutical preparation as claimed in claim 33, wherein the pharmaceutically active ionic peptide compound is D-63153, and the ~~amount~~ concentration thereof is about 25 mg/ml, and in that the inorganic salt is sodium chloride, and the concentration thereof is about 0.1% (weight/volume).

Claim 36 (Previously Presented): The method for producing a pharmaceutical preparation as claimed in claim 33, further comprising the step of sterilization of the peptide formulation by irradiation with gamma rays or electron beams takes place.

Claim 37 (Previously Presented): The method for producing a pharmaceutical preparation as claimed in claim 33, where the production of the peptide formulation takes place with use of aseptic procedures.

Claim 38 (Currently Amended): A kit for producing a pharmaceutical preparation, comprising ~~a previously fixed amount X~~ from 5 to 50 ~~in~~ mg per ml of the finished preparation of a pharmaceutically active ionic peptide compound having a length of from 8 to

12 amino acids in lyophilized form and ~~of~~ an aqueous solution of an inorganic or acetic acid salt ~~in a previously fixed concentration Y %~~ at a concentration of from 0.01% to about 0.9% (weight/volume).

Claim 39 (Previously Presented): The kit as claimed in claim 36, wherein the pharmaceutically active peptide compound is D-63153 in lyophilized form.

Claim 40 (Previously Presented): The kit as claimed in claim 36, wherein the D-63153 lyophilizate additionally comprises mannitol.

Claim 41 (Previously Presented): The kit as claimed in claim 36, wherein the inorganic salt is sodium chloride.

Claim 42 (Currently Amended): The kit as claimed in claim 36 wherein the ~~amount X~~ concentration of D-63153 is about 25 mg per finished preparation and the concentration of the aqueous sodium chloride solution is about 0.1% weight/volume.

Claim 43 (Currently Amended): A method for treating a patient with a pharmaceutically active peptide compound, wherein a pharmaceutical preparation as claimed in claim 1 is administered subcutaneously or intramuscularly to the patient ~~by means of a syringe~~.

Claim 44 (Previously Presented): The method as claimed in claim 43 wherein the administered pharmaceutical preparation displays a sustained pharmaceutical activity.

Claim 45 (Previously Presented): The method as claimed in claim 43 wherein the administered pharmaceutical preparation displays a sustained pharmaceutical activity for at least 4 weeks.

Claim 46 (Previously Presented): The method as claimed in claim 43 wherein the administered pharmaceutical preparation displays a sustained pharmaceutical activity for at least 8 weeks.

Claim 47 (Previously Presented): The method as claimed in claim 43 wherein the administered pharmaceutical preparation displays a sustained pharmaceutical activity for at least 12 weeks.

Claim 48 (Previously Presented): A method for treating a hormone-dependent disorder in a patient by subcutaneous or intramuscular administration of a pharmaceutical preparation as claimed in claim 1 in a patient requiring this.

Claim 49 (Previously Presented): A method for treating prostate cancer in a patient by subcutaneous or intramuscular administration of a pharmaceutical preparation as claimed in claim 1 in a patient requiring this.

Claim 50 (Withdrawn): A method for treating breast cancer in a patient by subcutaneous or intramuscular administration of a pharmaceutical preparation as claimed in claim 1 in a patient requiring this.

Claim 51 (Withdrawn): A method for treating uterine myomas in a patient by subcutaneous or intramuscular administration of a pharmaceutical preparation as claimed in claim 1 in a patient requiring this.

Claim 52 (Withdrawn): A method for treating endometriosis in a patient by subcutaneous or intramuscular administration of a pharmaceutical preparation as claimed in claim 1 in a patient requiring this.

Claim 53 (Withdrawn): A method for treating precocious puberty in a patient by subcutaneous or intramuscular administration of a pharmaceutical preparation as claimed in claim 1 in a patient requiring this.

Claim 54 (Withdrawn): A method for modifying the reproductive function in a patient by subcutaneous or intramuscular administration of a pharmaceutical preparation as claimed in claim 1 in a patient requiring this.

Claim 55 (Previously Presented): The pharmaceutical preparation as claimed in claim 1 wherein the mixture of the pharmaceutically active ionic peptide compound and of the aqueous solution of the inorganic salt or of the acetic acid salt is a molecular-dispersed or colloidal mixture which may be of liquid to semisolid consistency.

Claim 56 (Previously Presented): The pharmaceutical preparation as claimed in claim 1 wherein a colloidal dispersion is formed by reconstitution.

Claim 57 (Previously Presented): The pharmaceutical preparation as claimed in claim 1 wherein a colloidal dispersion is formed by storage or leaving to stand after reconstitution and changes its viscosity as a function of time and thus improves the reproducibility of the delayed release of active ingredient.

Claim 58 (Previously Presented): A kit comprising a lyophilized pharmaceutically active peptide optionally together with one or more pharmaceutically acceptable excipients or additives, and a low-concentration aqueous solution of an inorganic salt.

Claim 59 (Previously Presented): The kit as claimed in claim 58, wherein the lyophilized pharmaceutically active peptide is D-63153.

Claim 60 (Previously Presented): The kit as claimed in claim 58, wherein the inorganic salt is sodium chloride.

SUPPORT FOR THE AMENDMENTS

Claims 1, 16-18, 20-22, 25-27, 29, 30, 32, 33, 35, 38, 42, and 43 have been amended.

Claims 6, 7, 15, 19, 23, 24, 28, and 33 have been canceled.

The amendment to Claim 1 is supported by original Claims 6, 7, 15, 23, 24, and 33. The amendment of Claims 16-18, 20-22, 25-27, 29, 30, 32, 33, 35, 38, 42, and 43 is supported by the corresponding claims as originally filed. The specification and Claim 32 have also been amended to correct clear typographical errors, which find support throughout the original specification.

No new matter has been added by the present amendments.